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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,742	02/09/2004	Ashley M. Classen	15181.027	9209

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EXAMINER
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BUSTAMANTE, ERIK J

ART UNIT	PAPER NUMBER
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3766

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/774,742

Applicant(s)

CLASSEN ET AL.

Examiner

Erik J. Bustamante

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 63-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 6-12, 24-26, and 30-62 is/are rejected.
- 7) ☒ Claim(s) 3-5, 13-23 and 27-29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/9/04.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I, claims 1-62 in the reply filed on 10/10/2006 is acknowledged.
2. Claims 63-70 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/10/2006.

### ***Information Disclosure Statement***

3. All information disclosure statements (IDS) submitted to the Office are in compliance of 37 CFR 1.97. All the references cited are in compliance with the provisions of 37 CFR 1.98. Accordingly, the information disclosure statements are being considered by the examiner.

### ***Claim Objections***

4. Claims 2,13,14,30 are objected to because of the following informalities:
  - In claim 2 "the respective locations" lacks sufficient antecedent basis
  - In claim 13 "the active RF electrode", "the anesthetic pumping device", and "the RF generator" lack sufficient antecedent basis
  - In claim 14 "the RF signal generator" lacks sufficient antecedent basis
  - In claim 30, "the active electrode" lacks sufficient antecedent basis.Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 8-11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear in regards to claims 8, whether or not the applicant is trying to claim all the parameters or at least one. Appropriate clarification/correction is required.

7. Claims 30-62 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant is attempting to invoke 112<sup>th</sup> sixth paragraph protection; however, claim 30 is unclear whether the "means for" is referring to "adapted to connect with the electrode" or "administering a liquid substance."

8. Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant is attempting to invoke 112<sup>th</sup> sixth paragraph protection; however, claim 42 is unclear whether the "means for" is referring to "signal generating" or "setting signal parameter values."

9. Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant is attempting to invoke 112<sup>th</sup> sixth paragraph

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protection; however, claim 43 is unclear whether the "means for" is referring to "readout" or "providing parameter value information."

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-2, 6-12, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over SILBERSTONE et al (5,052,391) in view of GREENGRASS et al (5,976,110), and further in view of SMITH (6,010,467).

Regarding claims 1,2,6, SILBERSTONE discloses attaching an active and a dispersive percutaneous probe at respective active and dispersive locations (Col 3 lines 29-36); generating a first pulsed RF signal configured according to a first protocol for coupling to the active and dispersive probes to verify the location of the peripheral nerve (Col 2 lines 35-48; Col 7 lines 54-65); and generating a second pulsed RF signal configured according to a second protocol after the first pulsed RF signal is withdrawn, to modify propagation of pain sensation in the peripheral nerve without ablation thereof (Col 8 lines 8-20). However, SILBERSTONE does not disclose that the percutaneous probe includes an RF cannula having a conductive spatulate blade conformably attached to a dorsal side of a curved, blunt-ended tubular tip portion of the RF cannula.

REENGRASS teaches an RF cannula (12) for positioning near a peripheral nerve (Col 2 lines 13-18). REENGRASS further teaches that it is well known in the art to combine a cannula with an electrical stimulator for nerves (Col 1 lines 40-68). REENGRASS teaches that this is done so that anesthetics can be administered "in conjunction with providing electrical stimulation through the electrodes in order to control pain (Col 1 lines 45-46)."

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used an RF cannula in the method of SILBERSTONE in view of the teachings of REENGRASS for the purpose of controlling pain.

The method of SILBERSTONE as modified by REENGRASS renders the claimed invention as obvious with the exception that a conductive spatulate blade is conformably attached to a dorsal side of a curved blunt-ended tubular tip portion of the RF cannula.

SMITH teaches in a method/apparatus for treating facial pain, the use of "a spatula/spade like" extension (14) protruding from a wand used to identify sources of pain in the face (Col 1 lines 61-67; Col 2 lines 36-46). SMITH specifically teaches that it can be used "to locate more precisely the trigger point" of pain (Col 1 lines 66-67).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have attached a conductive spatulate blade to the RF cannula used in the method of SILBERSTONE as modified by REENGRASS,

in light of the teachings of SMITH for the purpose of locating precisely the trigger points of pain.

Regarding claim 7, SILBERSTONE discloses stimulating below a normal threshold of pain (Col 2 lines 38-39).

Regarding claim 8, *under the best interpretation of the Examiner*, SILBERSTONE discloses including at least a pulse amplitude, a pulse repetition rate (deemed to be synonymous with frequency), and a pulse duration (Col 4 lines 15-31; Col 6 lines 14-21).

Regarding claim 9, SILBERSTONE discloses shifting the amplitude to a threshold of sensation (Col 7 lines 54-65). SILBERSTONE alone or modified by GREENGRASS and/or SMITH does not render obvious the specific pulse repetition rate of 50 Hz or a pulse duration of 10 ms. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have use a pulse repetition rate of 50 Hz and pulse duration of 10 ms, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

With respect to claim 10, SILBERSTONE as modified by GREENGRASS and SMITH renders the claimed invention as obvious except for the specific signal parameter recited in the claim. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used those paramaters, since it has been held that discovering an optimum value of a result

effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

With respect to claim 11, SILBERSTONE as modified by GREENGRASS and SMITH render the claimed invention as obvious with the exception of setting the pulse repetition rate to a one shot pulse. However, the examiner takes the position that said modification would have been obvious to one of ordinary skill in the art at the time the invention was made as a matter of design choice.

With respect to claim 12, SILBERSTONE as modified by GREENGRASS and SMITH render the claimed invention as obvious with the exception of removing the output of the RF signal generator if monitoring the response of the patient indicates an incorrect location. However, the examiner takes the position that it would have been obvious to one of ordinary skill in the art at the time the invention was made to remove the output of the signal generator if the incorrect location was determined.

With respect to claims 24-26, the limitations in these claims are interpreted as describing an intended use and are deemed to not be a positive limitation.

12. Claims 30-41,44,45,49, 50-52, 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over SILBERSTONE in view of the applicant's disclosure and in further view of SMITH.

Regarding claims 30,44,49, and 52, *as best interpreted by the Examiner*, SILBERSTONE discloses a generator (20) and a set of RF percutaneous probes



(22,24,12,14; Fig 1). However, SILBERSTONE does not disclose that the probes should be in the form of an RF cannula with a spatulate blade.

In Fig 3, the applicant discloses in the specification that the prior art teaches an RF cannula (110) for insertion into a patient's skin (page 13 lines 6-25).

Applicant further discloses that the prior art RF cannula as disclosed contains a means adapted to connect with an active electrode and for liquid administration (116). Regarding claims 44 and 52, the applicant discloses as prior art an RF cannula having an insulated tubular body (114); a hub at a first end of the tubular body (120); and a blunt-ended and conductive tubular tip (122) extending from a second end of the insulated tubular body

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used an RF cannula in the apparatus of SILBERSTONE in view of the applicant's admission of prior art as described above.

The apparatus of SILBERSTONE as modified by the applicant's disclosure renders the claimed invention as obvious with the exception that a conductive spatulate blade is conformably attached to a dorsal side of a curved blunt-ended tubular tip portion of the RF cannula.

SMITH teaches in a method/apparatus for treating facial pain, the use of "a spatula/spade like" extension (14) protruding from a wand used to identify sources of pain in the face (Col 1 lines 61-67; Col 2 lines 36-46). SMITH

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specifically teaches that it can be used "to locate more precisely the trigger point" of pain (Col 1 lines 66-67).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide and have attached a conductive spatulate blade to the RF cannula used in the apparatus of SILBERSTONE as modified by the applicant's disclosure, in light of the teachings of SMITH for the purpose of locating precisely the trigger points of pain.

With regards to claims 31-41, the claims are not regarded as positive limitations since they only modify the phrase "for generating" in independent claim 30, which is regarded by the examiner as intended use and not given patentable weight.

With regards to claims 45 and 53, the apparatus of SILBERSTONE as modified by the applicant's disclosure and SMITH render the claimed invention as obvious with the exception of the tubular tip extending approximately one centimeter from the tubular body and curving the tip ten to thirty degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the tubular tip extend approximately one centimeter from the tubular body and curve the tip ten to thirty degrees, since it has been held that manipulating dimensions is within skill of one of ordinary skill in the art. *In Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984)

With regards to claims 49 and 57, the applicant has disclosed that the prior art includes an orifice (116).

In the matter of claims 50,51,58, and 59, the applicant admits that the cannula is adapted to receive an RF electrode (page 13 lines 18-21).

***Allowable Subject Matter***

13. Claims 3-5, 13-23, and 27-29 are objected to as being dependent upon a rejected base claim but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. Claims 42-43, 46-48, 53-56, and 60-62 would be allowable if rewritten to overcome the rejections(s) under 35 U.S.C. 112 2<sup>nd</sup> paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Erik J. Bustamante whose telephone number is 571-272-8820. The examiner can normally be reached on Mon-Fri (7:30 - 11:30 AM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

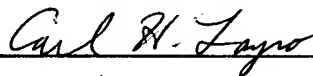
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